UNITED STATES DISTRICT COURT

DISTRICT OF MAINE

KAYLA DOHERTY,	)	
	)	
PLAINTIFF	)	
	)	
v.	)	
	)	
MERCK & CO., INC. and UNITED STATES OF AMERICA,	)	
	)	**CIVIL NO. 1:15-cv-129-DBH**
DEFENDANTS	)	
	)	
and	)	
	)	
ATTORNEY GENERAL FOR THE STATE OF MAINE,	)	
	)	
INTERVENOR DEFENDANT	)	

CERTIFICATE OF QUESTIONS OF STATE LAW TO THE MAINE SUPREME JUDICIAL COURT SITTING AS THE LAW COURT

After oral argument on December 3, 2015, the United States District Court for the District of Maine finds that this case involves questions of law of the State of Maine that may be determinative of the cause and that there are no clear controlling precedents thereon in the decisions of the Maine Supreme Judicial Court. See M.R. App. P. 25(a). Although this case is at an early stage (the defendants' motions to dismiss the First Amended Complaint have just been denied without prejudice), a decision by the Law Court that no recovery is available to the plaintiff under Maine law even if all her factual allegations are true (the defendants' contention in their motions to dismiss that I rejected) would be determinative of the cause and would end the lawsuit now.

Specifically, there is a question whether Maine's Wrongful Birth statute, 24 M.R.S.A. § 2931 (2015)—added in 1986 to the Maine Health Security Act[1] as part of "An Act Relating to Medical and Legal Professional Liability," L.D. 2400, § 16 (112th Legis. 1986)[2]—applies to drug manufacturers and distributors; and, if it does not, the scope (as it applies to drug manufacturers and distributors) of an earlier Law Court decision, Macomber v. Dillman, 505 A.2d 810 (Me. 1986), that limits damages against health care providers for failed sterilization. There is also a definitional question regarding the scope of the statutory language in section 2931(2) allowing limited damages for a "failed sterilization procedure"—specifically, whether it covers the method of birth control at issue in this case. The plaintiff contends that the "open courts" provision of article 1, section 19 of the Maine Constitution bears upon the answers.

The style of the case is *Kayla Doherty, Plaintiff, v. Merck & Co., Inc., and United States of America, Defendants*. See M.R. App. P. 25(b). The Attorney General for the State of Maine has intervened to defend the constitutionality of Maine's Wrongful Birth statute. See 28 U.S.C.A. § 2403(b) (2006).

[1] The Maine Health Security Act appears in Title 24 of the Maine Revised Statutes, which generally deals with insurance and health care providers.

[2] The original draft of the bill, L.D. 2065, § 16 (112th Legis. 1986) ("An Act to Expedite the Resolution of Professional Negligence Claims, to Amend Selective Provisions of the Maine Health Security Act and to Abolish the Discovery Rule in Claims Against Health Practitioners, Health Providers and Attorneys"), did not include a limited recovery provision for failed sterilization procedures that resulted in the birth of a healthy child. See id. After the Law Court's decision in Macomber v. Dillman, 505 A.2d 810 (Me. 1986), however, a new draft of the bill effectively codified the Macomber decision. See Legis. Rec. H-1466-69 (2d Reg. Sess. 1986).

A statement of facts showing the nature of the case and the circumstances out of which the questions of law arise is attached as *Appendix A*. See M.R. App. P. 25(b).

The questions of law to be answered are:

1. Does the protection of Maine's Wrongful Birth statute, 24 M.R.S.A. § 2931, extend to the defendant Merck & Co., Inc., as a drug manufacturer and distributor?
2. If not, does the Law Court's decision in Macomber v. Dillman, 505 A.2d 810 (Me. 1986), which concerned a failed sterilization by a health care provider, apply to the plaintiff Kayla Doherty's claim against Merck as a drug manufacturer and distributor?
3. Does Maine's Wrongful Birth statute prohibit all recovery for Doherty against both defendants (Merck if it is covered by the statute, see question one, supra) because of the nature of the procedure she underwent? Or does the statute allow Doherty to proceed with her claims but limit the recoverable damages to her expenses incurred for the procedure and pregnancy, pain and suffering connected with the pregnancy, and loss of earnings during pregnancy?

Guided by the Law Court's observation "that promotion of federal-state comity counsels that '[w]herever reasonably possible, the state court of last resort should be given opportunity to decide state law issues on which there are no state precedents which are controlling or clearly indicative of the developmental course of the state law,'" Dinan v. Alpha Networks Inc., 2013 ME 22, ¶ 12, 60

A.3d 792 (alteration in original) (quoting White v. Edgar, 320 A.2d 668, 675 (Me. 1974)), I respectfully ask for instructions concerning these questions of Maine law, see 4 M.R.S.A. § 57 (1989 & Pamph. 2015); M.R. App. P. 25(a), now that I have denied (pending the Law Court's answers to the foregoing questions of Maine law) the defendants' motions to dismiss that assert that Maine law prevents any recovery by this plaintiff.

I suggest that the plaintiff Kayla Doherty be treated as the appellant before the Law Court, see M.R. App. P. 25(b), because she requested the certification.

The Clerk of this Court is hereby **DIRECTED** to cause twelve (12) copies of this Order and the Appendix to be certified, under official seal, to the Maine Supreme Judicial Court sitting as the Law Court. It is **FURTHER ORDERED** that the Clerk of this Court be, and is hereby, authorized and directed to provide, without any cost to the Law Court, upon written request of the Chief Justice or the Clerk thereof, copies of any and all filings of the parties herein and of the docket entries pertaining to this case.

SO ORDERED.

DATED THIS 7TH DAY OF JANUARY, 2016

/s/D. Brock Hornby
D. BROCK HORNBY
UNITED STATES DISTRICT JUDGE

APPENDIX A

STATEMENT OF FACTS SHOWING THE NATURE OF THE CASE AND THE CIRCUMSTANCES OUT OF WHICH THE QUESTIONS OF LAW ARISE

The parties have quarreled over the adequacy of the First Amended Complaint under federal pleading standards. Primarily, the defendants challenged the plaintiff's ability to characterize her procedure as "sterilization"—the term used in the Wrongful Birth statute and in Macomber. But I denied the defendants' motions to strike and to dismiss, and I conclude as a matter of federal law that the following factual allegations are properly pleaded. The plaintiff's factual allegations are therefore taken as true for the purpose of testing the defendants' argument that Maine law allows no recovery to the plaintiff even if her allegations are proven.[3] *Notably, I have removed any characterization of the plaintiff's procedure (leaving in place its factual description) and also some surplusage not material to the certified questions.*

The plaintiff, Kayla Doherty of Pittsfield, Maine, visited the Lovejoy HealthReach Community Health Center (HRCHC) in Albion, Maine, on January 26, 2012, to inquire about birth control options. Lovejoy HRCHC is a covered entity pursuant to the Federally Supported Health Centers Assistance Act (FSHCAA) under the Federal Tort Claims Act (FTCA), 28 U.S.C.A. §§ 2671-2680 (2006). The FSHCAA extends the FTCA's liability protections for

[3] *If the case proceeds because the Law Court rejects the defendants' interpretation of Maine's Wrongful Birth statute, then the defendants will have the opportunity to challenge the plaintiff's allegations in their Answers.*

medical malpractice to Lovejoy HRCHC and its employees. At the time, Doherty was twenty years old and wanted to avoid having a baby until she had economic stability. At Lovejoy, Doherty saw Dr. Amanda Ruxton, D.O., an employee acting within the scope of her employment who is covered by the FTCA through the FSHCAA. Dr. Ruxton recommended the use of an implantable drug, either Implanon or Nexplanon, manufactured and distributed by the defendant, Merck & Co., Inc. Merck is a New Jersey corporation that tests, develops, manufactures, distributes, licenses, labels, and markets those drugs. On February 28, 2012, Dr. Ruxton purported to carry out the procedure that she had recommended to Doherty by using a syringe[4] to insert either Implanon or Nexplanon into Doherty's arm.

Implanon is a four-centimeters-long[5] single rod with an ethylene vinylacetate copolymer core containing sixty-eight milligrams of etonogestrel, a type of hormone (progestin) effective at inhibiting ovulation and preventing pregnancy. It is inserted just under the skin on the inner side of a woman's arm between the bicep and tricep muscles using a syringe-like applicator. In 2011, Merck obtained FDA approval for Nexplanon—a product nearly identical to Implanon except that the Nexplanon rod contains fifteen milligrams of barium sulfate to make it radiopaque, meaning it will show up on an x-ray.

[4] Defendant Merck asserts that the more technically correct term for this device is a "single-use product applicator"—roughly the language used in the FDA-product labeling for Implanon and Nexplanon.

[5] The FDA-product labeling information for Implanon and Nexplanon filed by Merck with its motion to dismiss states that the rod is four centimeters long and two millimeters wide.

Both Implanon and Nexplanon are intended to be long lasting and irreversible for a period of at least three years,[6] unless removed earlier by a surgical procedure performed by a physician. Merck allegedly knew or should have known that, due to the design of the rod's applicator, both products have a history of failed insertion attempts—the failure remaining unknown to the physician. Physicians can erroneously believe that the rod has been successfully inserted because they fail to recognize that the rod remained stuck in the applicator after the procedure. Unknown failed insertion could lead to unplanned pregnancy. Nevertheless, Merck allegedly promoted use of the drugs with inaccurate statements regarding their quality and fitness, and failed to conduct adequate pre- and post-marketing studies of the safety and effectiveness of Implanon's and Nexplanon's designs, warnings, and insertion methods.

In her treatment of Doherty, Dr. Ruxton allegedly was negligent in a number of respects, including failing to explain risks and dangers to Doherty; failing to examine Doherty's arm after insertion to see if insertion of the rod was successful; failing to give Doherty any handouts or information regarding the product, including information on failed insertion and how to check for proper positioning of the rod on a regular basis; and failing to keep an accurate medical record stating which arm had received the insertion. A positive pregnancy test at the Lovejoy HRCHC on October 16, 2013, confirmed that Doherty, then age twenty-one, had become pregnant. Despite extensive effort, Lovejoy staff could

[6] The FDA-product labeling information for Implanon and Nexplanon filed by Merck with its motion to dismiss states that Implanon and Nexplanon are "long-acting" and "reversible."

not find the rod in Doherty's arm or determine the implantation site.[7] Lovejoy cancelled Doherty's next appointment and sent her to Inland Hospital for treatment. Ultrasounds on October 23, 2013, at Inland Hospital could not find the rod in either of Doherty's arms. On about October 24, 2013, a Lovejoy nurse told Doherty that "Dr. Ruxton believes it was never inserted."

On June 9, 2014, Doherty underwent a long and painful delivery producing a healthy baby boy. Doherty claims to have suffered damages as a result of her unintended pregnancy and birth of her child. In connection with her pregnancy, Doherty suffered nausea, mental and physical pain and suffering, insomnia, swelling, and weight gain. She was required to attend multiple medical appointments and incurred resulting expenses, missed time from work, and thus lost wages. Since giving birth, she has received mental health counseling and has suffered emotional distress from rearing a child as a single mother without adequate preparation, planning, and economic resources. Doherty, already a certified nursing assistant, had hoped to attend nursing school and establish herself in the profession before starting a family.

Doherty has sued the United States for Dr. Ruxton's professional negligence and failure to obtain Doherty's informed consent. Pursuant to the FTCA, the United States is liable for Dr. Ruxton's conduct "in the same manner and to the same extent as a private individual under like circumstances." 28 U.S.C.A. § 2674(a); see id. § 1346(b)(1). In connection with Implanon and Nexplanon, Doherty has sued Merck for strict product liability, breach of express

[7] Defendant Merck would prefer to characterize this as the "insertion" site.

and implied warranties, negligence, and negligent misrepresentation. Predicting that the defendants would invoke Maine's Wrongful Birth statute, 24 M.R.S.A. § 2931, to shield themselves from liability, Doherty also seeks a declaratory judgment that section 2931 is unconstitutional under state and federal law if it is interpreted to bar her from any recovery for her claims (as the defendants contend). I granted the motion of the Attorney General of the State of Maine to intervene to defend the constitutionality of the Maine statute.

Both Merck and the United States filed motions to dismiss the lawsuit, asserting that even if Doherty's factual allegations are true, section 2931 bars all of Doherty's claims—including Doherty's product liability claims—because the birth of a healthy child is not a legally cognizable injury under Maine law and Doherty's use of Implanon or Nexplanon does not fall within the statutory exception of providing limited relief for a "failed sterilization procedure." Id. § 2931(2). After hearing oral argument, I denied their motions from the bench on December 3, 2015, pending answers to questions of Maine law regarding Maine's Wrongful Birth statute by the Law Court.